DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 7, 2015

GE Healthcare
Robert Casarsa
Regulatory Affairs Leader
8200 West Tower Ave.
Milwaukee, Wisconsin 53223

Re: K142840
Trade/Device Name: Unity Network ID V7
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: December 5, 2014
Received: December 8, 2014

Dear Robert Casarsa,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Unity Network ID V7

Indications for Use:

The Unity Network ID is indicated for use in data collection and clinical information management through networks with independent bedside devices. The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

Prescription Use_X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Sub part D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 26, 2014
Submitter:	GE Healthcare 8200 W. Tower Ave. Milwaukee, WI 53223
Primary Contact Person:	Robert Casarsa Regulatory Affairs Leader GE Medical Systems Information Technologies, Inc. Email: robert.casarsa@ge.com Ph: (414) 362-3063 Fax: (414) 262-2585
Secondary Contact Person:	Douglas Kentz Regulatory Affairs Director GE Medical Systems *Information Technologies*, Inc. Ph: (414) 362-2038
Device Trade Name:	Unity Network ID
Common/Usual Name:	Physiological Patient Monitor
Classification Names: Product Code:	21 CFR 870.2300 Monitor, Physiological, Patient (without arrhythmia detection or alarms) MWI
Predicate Device(s):	Unity Network ID V6 K103432
Device Description:	The Unity Network ID system communicates patient data from sources other than GE Medical Systems Information Technologies, Inc. equipment to a clinical information system, central station, and/or GE Medical Systems *Information Technologies* Inc. patient monitors. The Unity Network ID acquires digital data from eight serial ports, converts the data to Unity Network protocols, and transmits the data over the monitoring network to a Unity Network device such as a patient monitor, clinical information system or central station.
Intended Use:	The Unity Network ID is indicated for use in data collection and clinical information management through networks with

	independent bedside devices. The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.
Technology:	The device converts the output from independent bedside device's RS-232 protocol into the Unity Network protocol
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Unity Network ID V7 and its applications were tested to, and comply with, applicable voluntary standards. The Unity Network ID V7 was tested to assure that the device meets its design specifications. Testing included all new or modified features. The following quality assurance measures were applied to the development and testing of the of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, Unity Network ID V7, did not require clinical studies to support substantial equivalence.
Comparison:	Hardware: 1) No change to the Unity Network ID hardware 2) Create interface cables for the newly supported devices Software: 1) Add interface support for the following third party devices: (a) Drager Evita infinity V500 (K093633) (b) Radiometer TCM4 (K043003) (c) Radiometer TCM40 (K043003) (d) Radiometer TCM CombiM (K093154)

	(e) Radiometer TCM Tosca (K093154) 2) Add interface support for the following GE Healthcare devices: (a) Carescape R860 (not sold in USA) (b) Carestation 600 (not sold in USA) 3) Support of additional parameteres from currently supported devices: Pulsion PiCCO plus (K060898): Cardiac Index (CI), Continuous Cardiac Index (CCI) and System Vascular Resistance Index (SVRI) Pulsion PiCCO2 (K072735): Cardiac Index (CI), Continuous Cardiac Index (CCI) and System Vascular Resistance Index (SVRI) GE Datex-Ohmeda Aisys (K061609): volume waveform GE Datex-Ohmeda Avance (K040743): volume waveform GE Datex-Ohmeda Engstrom (K062710): volume waveform
Conclusion:	GE Healthcare considers the Unity Network ID V7 to be as safe, as effective, and its performance is substantially equivalent to the predicate device(s).